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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,875	03/02/2002	Hans Schuhbauer	HUBR-1206 (10202655)	4984
24972	7590	10/07/2003	EXAMINER	
FULBRIGHT & JAWORSKI, LLP			YOUNG, MICAH PAUL	
666 FIFTH AVE			ART UNIT	PAPER NUMBER
NEW YORK, NY 10103-3198			1615	9
DATE MAILED: 10/07/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/088,875	SCHUHBAUER ET AL.
	Examiner Micah-Paul Young	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 27-52 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 27-52 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3.7</u> .	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosure Statements dated 3/2/02 and 1/31/03.

Claim Objections

1. Claim 39 is objected to because of the following informalities: the word heaxaquoaluminum is misspelled *hexaquoaluminum* and the closing parenthesis is missing and in the wrong position for the formula of hexacyanoiron. The formula should read [H₄(Fe(CN)₆)]. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27 – 31, 33, 34, 37, 40, 42, 43, 46 – 50 – 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich et al (USPN 5,691,379). The claims are drawn to a sustained release formulation of α -lipoic acid and/or derivative, a cationogenic polymer and an additional acidic component. The formulation further comprises fillers, and other excipients well known in the art.

Ulrich discloses a dihydrolipoic acid sustained release formulation comprising various biocompatible cellulosic polymers, acetic acid, and other fillers, lubricants and plasticizers known in the art (abstract; col. 48 – 64; col. 7, lin. 34 – col. 8, lin. 47). The formulation can be formed into medicaments such as capsules, pellets and pills, or in the form of a lotion (col. 9, lin. 42 – 48). The reference discloses methods for the administration of the formulation (col. 9, lin. 53 – col. 10, lin. 11). The formulation is granulated along with the carrier materials and processed at a temperature between 20 and 80 degrees Celsius (col. 10, lin. 23 – col. 11, lin. 3). These disclosures along with others render the claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 35, 36, 41, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al (USPN 5,691,379) in view or Ulrich et al (USPN 5,100,919). The claims are drawn to a sustained release formulation recited particular concentrations and proportions of the essential components, namely a cationogenic polymer, a α -lipoic acid and/or a derivative, and a further acid. The claims also are drawn to a method of production comprising combining the components along with other well known excipient such as filler, plasticizers and the like, wet granulating the combination and drying the granules between 5 and 50°C, and forming a tablet.

With regard to claims 35, 36 and 41, which recite limitations to specific concentrations, ratios and proportions, it is the position of the examiner that such limitations do not impart patentability on the claims barring a showing of criticality. The prior art discloses a general combination of the elements, and applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to claim 44, which recites the method of production, the reference discloses a similar procedure, yet does not disclose the proportion of part 1). It is the position of the

examiner that though the reference does not disclose the particular proportions recited in the claims, a skilled artisan would still be motivated to follow the processing steps of combining the active, with the excipients, granulating and drying them at a temperature between 20 and 80 °C, since wet granulation and tableting are so well known in the art. Ulrich '919 discloses tablets formed from wet granulation of the ingredients and drying overnight at a temperature of 45 °C (examples).

As discussed above the proportion of the active and inactive components could be determined through routine experimentation. With this in mind a skilled artisan would have been motivated by the suggestion of Ulrich '379 to granulate and dry the granules at the desired temperature of Ulrich '919. It would have been obvious to combine the tablet the ingredients of Ulrich '379 with the process of Ulrich '919 with an expected result of a tablet with antioxidant properties.

5. Claims 32, 38, 39 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al (USPN 5,691,379) in view of Weithman et al (USPN 5,318,987), Bethge et al (USPN 5,621,117), Prigal (USPN 3,678,149) and Matsuoka et al (USPN 3,697,647). The claims are drawn to a pharmaceutical dosage form comprising a α -lipoic, a cationogenic polymer, and another acid. The α -lipoic acid can be present with cation such as iron, copper and palladium. The acid can be a Lewis acid, or a complex acid. The composition can be in the form of a food supplement as well.

As discussed above Ulrich discloses essential elements of the claimed invention. The reference discloses α -lipoic compound, biopolymer and secondary acid. Lacking in the reference

are disclosures of the specific cations present in the active compound salt, the complex or Lewis acids, and the food supplement presentation.

Weithmann et al discloses an antioxidant composition comprising a α -lipoic acid derivative (col. 27, lin. 1). Cations present in the salts of the salts of the compound are alkaline earth metals such as zinc, iron and aluminum (col. 10, lin. 45 – 55). The composition further comprises further tableting excipients such as fillers sugars and tableting agents well known in the art (col. 12, lin. 5 – 34).

Bethge et al discloses a method for racemizing α -lipoic acid composition comprising inorganic and /or organic Lewis acids that are added to the α -lipoic compounds (col. 2, lin. 56 – 65; examples).

Prigal discloses a composition comprising hexacyanoiron in combination with antioxidants (col. 1, lin. 26 – col. 2, lin. 35; examples).

Matsuoka et al discloses a feed composition comprising α -lipoic compositions along with their cationic salts and other antioxidants (col. 12, lin. 19 – 30; examples).

Taking the prior art not consideration a skilled artisan would have been motivated to combine the salts of Weithmann with the composition of Ulrich in order to improve the solubility; combined the acids of Bethge and Prigal in order to properly solubilize the α -lipoic acid compounds; and would have been motivated to include the resultant formulation into a food composition as seen in Matsuoka in order to impart antioxidant properties into consumables. It would have been obvious to a skilled artisan to combine the teachings and suggestions of the art with an expected result of food product where the α -lipoic acid compound is properly solubilized and has better bioavailability, and in turn has antioxidant properties.

Correspondence

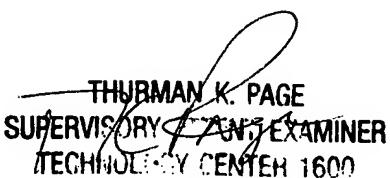
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young



THURMAN K. PAGE
SUPERVISORY STANT EXAMINER
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